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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,422	08/04/2000	Berton Gunter	MERK-0004/20671	1928
7590	07/26/2004		EXAMINER ZEMAN, MARY K	
Steven H Meyer Woodcock Washburn Kurtz Mackiewicz & Norris LLP One Liberty Place 46th Floor Philadelphia, PA 10103			ART UNIT 1631	PAPER NUMBER

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/632,422	GUNTER, BERTON	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mary K Zeman	1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2 and 4-58 is/are pending in the application.
- 4a) Of the above claim(s) 10-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Claims 1, 2 and 4-58 are pending in the application

Claims 10-58 stand withdrawn from consideration and should be canceled in response to the final rejection.

Applicant's arguments filed 5/19/04 have been fully considered but they are not persuasive. Any rejection not repeated below has been withdrawn.

The IDS filed 5/19/04 has been entered and considered. An initialed copy of the form PTO-1449 is included with this action.

Claims 1, 2 and 4-6 remain rejected under 35 U.S.C. 102(e) as being anticipated by French et al. (USP 6,297,018).

Applicant argues that French et al. does not relate to analyzing the data from a stack of plates, but a single plate, and that French et al. only analyzes data in two dimensions. These arguments are not persuasive. Applicant is arguing limitations not present in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims do not require the processing of multiple sets of data, nor that the data is arranged in I, j, p formation. The data is required to be subject to "systemic and positional effects" This limitation is met by French. French et al. discuss in great detail at columns 47-70 how to compensate the raw assay data for systematic (background) and positional (edge, meniscus, position of detector in the well etc.) effects, how to score the compensated data, how to format it accordingly, and how to use it to identify biologically active agents by identifying data points that statistically deviate from other points in the formatted scored data.

Claims 7-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over French et al. as applied to claims 1, 2 and 4-6 above, in view of MATHSOFT.

Applicant's arguments regarding the applicability of MATHSOFT have been considered and are not persuasive. French et al is the primary reference regarding the steps of the method, and MATHSOFT is applied for the execution of certain statistical steps which Applicant admits can be performed by any software. Applicant argues that MATHSOFT does not use any of the

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specific data generated by the method, however, the data itself does not impart functionality to the program. The program can perform the steps on any data.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the MATHSOFT program is so well known in the art for the performance of routine statistical analysis that it is cited in the specification for such a reason. Therefore, it is well known to anyone in the art of data analysis and biostatistics.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

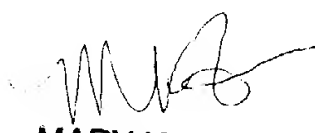
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P Woodward can be reached on (571) 272 0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
**MARY K. ZEMAN**  
**PRIMARY EXAMINER**  
09/16/04